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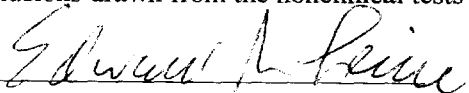


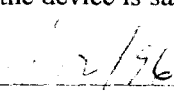
**510 (k) Summary
Safety and Effectiveness**

This summary of safety and effectiveness information has been prepared in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Name: Diagnostic Products Corporation
Address: 5700 West 96th Street
Los Angeles, California 90045-5597
Telephone Number: (213) 776-0180
Facsimile Number: (213) 776-0204
Contact Person: Edward M. Levine, Ph.D.
Manager of Clinical Affairs
Date of Preparation: January 12, 1996
Device Name: PSA Controls
Trade: Device intended as an aid in monitoring the performance
of DPC's Coat-A-Count® PSA IRMA.
Catalog Number: PSAC1, PSAC2, PSAC3
Classification: Class I device, 82-JJX (21 CFR 862.1660)
Manufacturer: Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, California 90045-5597
Establishment Registration Number: DPC's Registration Number is 2017183
Description of Device: DPC's PSA Controls are assayed tri-level
controls intended for use in the quality control of DPC's
Coat-A-Count PSA IRMA.
Intended Use of the Device: DPC's PSA Controls are designed for use as
an assayed quality control serum in the clinical chemistry
laboratory to monitor the accuracy and precision of the
Coat-A-Count PSA IRMA procedure. They are intended
strictly for in vitro diagnostic use.
Clinical Studies: Not applicable
Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the device is safe and effective.


Edward M. Levine, Ph.D.
Manager of Clinical Affairs


Date